PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	John E. Burnes et al.	Examiner:	J. L. Reidel
Serial No.	10/803,570	Group Art Unit:	3762
Filing Date:	March 17, 2004	Docket No.:	P-11471.00
Title:	APPARATUS AND METHODS OF ENERGY EFFICIENT, ATRIAL-BASED BI-VENTRICULAR FUSION-PACING		

DECLARATION UNDER 37 CFR 1.131 ANTEDATING A REFERENCE

We hereby declare the following:

1) We are currently and correctly named as an inventor in the pending patent application entitled APPARATUS AND METHODS OF ENERGY EFFICIENT, ATRIAL-BASED BI-VENTRICULAR FUSION-PACING, Serial number 10/803,570.

2) The invention disclosed within the above-referenced patent application was conceived of by us prior to June of 2002.

3) A written description of the invention is present in the laboratory notebooks of the inventor John E. Burnes with a date of entry as early as June of 2002 as well as subsequent entries (copies attached hereto as "Exhibit A" including at least one page from laboratory notebook number 10250 and number 11258).

4) An Invention Disclosure Form was completed that described the invention and was submitted to the Medtronic, Inc. legal department for consideration prior to June of 2003 (copy attached hereto as "Exhibit B").

5) The invention was not publicly disclosed or offered for sale prior to the filing date of the present patent application.

6) We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 12-Jan-2006

John E. Burnes

Date: 12-JAN 2006

Thomas J. Mullen

TLE Fusion Pacing - Timing of LVp

Project No.
Book No. 10250

Exhibit A (9.1)

rom Page No.

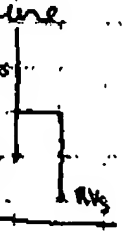
How to time LVp wrt RVs?

- What does the normal heart have for timing of dP/dtmax on LV + RV? to check in Lang.
- Assume dP/dtmax occurs near simultaneous in RV + LV
- Want to time delivery of LVp such that LV dP/dtmax occurs simultaneous w RV dP/dtmax intrinsic
- What implantable information gives us LVdP/dtmax?
  - crystals on LV lead
  - pressure directly or derived from RV
  - Z on the LV lead?

Fusion Pacing = Timing an LV pace based on an intrinsic RV sense

RVOT Fusion/Triggered = Fusion pacing w RV sense from RVOT

Adaptive Fusion = Pacing the LV before an RV sense occurs to ensure the LV has activated to be simultaneous w RV activation.



Fusion pacing for DHF &/or wide QRS

- alter activation sequences to alter filling & emptying patterns
- alter repolarization & perhaps relaxation w use of LV epi pacing
- AV coupling may be altered, resulting in altered filling / emptying

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witnessed & Understood by me,	Date	Invented by	Date

Alg for Fusion Pacing w LV Pre-excitation

Project No.
Book No. 11258

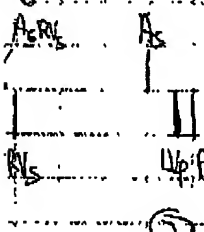
Exhibit A-1 (pg 1 of 2)

Page No.

sion pacing may require pacing the LV prior to an RV sense, especially r there is slow conduction from the LV pace to the complete LV contraction cell to cell or poor Purkinje)

e constant is the A pace or A sense
; we track the A-RV sense time, and know how far in front of the RV sense e need to pace the LV, the we can set the next LV pace to occur wrt he next A event (pace or sense) based on the previous A-RV sense.

this assumes minimal RA-RV time differences on a beat to beat basis
ore advanced algorithms could look at multiple RA-RV times to predict the next using Averages, weighted averages (time weighted, w most recent A-V having more weight)



Define LV_p wrt RV_s ! -20ms ⇒ LV pre-excitation time = 20ms

For beat ②: $A_s LV_p$ interval = $A_s RV_s$ from ① + LV pre-excitation time

If $A_s RV_s$ = 180ms, then $A_s LV_p$ delay for ② = 180ms - 20ms = 160ms

evice could monitor LV_p time to RV_s time to be sure it is staying consistent w the programmed desired LV pre-excitation time
If $LV_p RV_s$ is too short wrt LV_{pet}, the $A_s LV_p$ int could be shortened
If $LV_p RV_s$ is too long wrt LV_{pet}, the $A_s LV_p$ int could be lengthened

These modulations could be done on a beat-to-beat basis or conservatively over a number of beats (averaging)

This auto-adjustment may come into play w exercise induced RBB, especially RBBB
not even necessarily related to exercise
Could be adapted to RV fusion pacing as well
Could use RA as LA
Could automatically adjust for ~~LA or~~ RA pacing or RA sensing

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sed & Understood by me, | Date | Invented by Wm R. | Date

TLE Fusion Pacing (cont) Project No. Book No. 11256 Exhibit A (99)

om Page No.

This could be further enhanced by looking at Evoked responses or Twaves to determine if we are getting fusion.

Methods to detect fusion or loss thereof:
- ECG or EGM morphology
- Evoked response
- Twave morphology
- ARI - Local
  - Global
- Timing
- Periodic "poking" at the intrinsic $A\text{-}RV_S$ & $A\text{-}LV_S$

Can there be some rate adjustment here?
- rate dependant bundle branch blocks?
- as rate ↑, ARI_S may ↑, requiring $A\text{-}LV_P$ to be lengthened

Can we use other sensors to tell us we are doing this right?
- accelerometer
- pressure (LA or LV or RV)

ARI: Hypothesis
- No fusion ⇒ RV impulse gen = $RV\ ARI_{Int}$
  LV " " = $LV\ ARI_{Int}$
- Pacing from RV or LV ⇒ RV " " = $RV\ ARI_{pace}$
  LV " " = $LV\ ARI_{pace}$
- Fusion ⇒ RV impulse gen = $RV ARI_{Fusion}$ which is similar to $RV\ ARI_{Int}$
  LV " " = $LV ARI_{Fusion}$ which is between $RV ARI_{Int}$ & $LV ARI_{pace}$

↳ I should have data on this.

- Global EGMs may also be of use here.

We could predict the amount of tissue altered or excited by a pace by looking at the amount of Δ in EGM morphology, Twave area, ARI etc compared to the paced excitation or intrinsic excitation.

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Witnessed & Understood by me, Date Invented by N. J. ... Q Date

"Exhibit B"

Medtronic

Invention Disclosure Evaluation AND Analysis
Invention Disclosure Form

LB015
PHM
P-11471.00

WARNING
Please Handle this Document as a Confidential and Proprietary Document of Medtronic

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This is an MS Word Template form -- please complete it in Word if possible. If you must fill in the form by hand and the allotted space is not sufficient, use a separate sheet. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney.

Once complete, please print and sign the form, and forward it to the Patent Section of the Law Department, LC340.

Inventor(s) Full Name	Employee Number	Mail Stop	Home Address (Include Zip Code)
John E. Burnes	9868	CW210	1442 159th Ave NW, Andover, MN 55304
Thomas J. Mullen	34900	CW210	2033 135th Ln NE, Ham Lake, MN 55304

1. Title of Invention: System and Method for Bi-Ventricular Fusion Pacing

2. Abstract of the Invention including structure and/or method and process (250 words or less):

Cardiac resynchronization therapy is thought to gain much of its benefit by generating a more synchronous LV contraction through pacing of both the RV and LV. This method generally requires an AV delay that is shorter than the intrinsic AV interval. Fusion pacing is a previously proposed method of CRT pacing (P-8968, Hill) in which the LV is paced with respect to an RV sense such that the paced LV wavefront fuses with the intrinsic RV wavefront. However, the conduction times from the epicardial site of the LV lead to a large enough portion of the LV wall to generate a significant mechanical contraction may necessitate pre-excitation of the LV with respect to the RV sense to achieve an optimal fusion. This invention allows for LV pre-excitation with respect to the intrinsic RV sense through monitoring of A-RVsense times. The A-RVsense times are monitored on a beat by beat basis. The LV pace is delivered with respect to an A sense or pace. For each beat, the previous A-RVsense is noted, and the LV pace is delivered with respect to the current A event and the desired LV pre-excitation with respect to the previous RVsense. Variations of the method are proposed that allow for the use of multiple previous A-RVsense times to predict where the current LV pace should be placed. Furthermore, methods are proposed to monitor the amount of fusion

occurring with the pacing and automatically adjust the pacing parameters to achieve the desired amount of fusion.

3. Medtronic business unit to which the invention relates: CRM

4. Primary technology area to which the invention relates: Heart Failure

   Secondary technology areas to which the invention relates:

5. Primary therapy to which the invention relates: Cardiac Resynchronization Therapy

   Secondary therapies to which the invention relates:

6. Primary disease state to which the invention relates: Heart Failure

   Secondary disease states to which the invention relates:

7. Project Number: Q0047

   Project Name: Resynch Research

8. Why is the invention significant to the company? (250 words or less)

Development of a fusion pacing mode for CRT has several potential incremental benefits over standard CRT therapy with a short AV interval. These benefits will help improve the effectiveness and acceptance of CRT, These benefits include:

1) Single output V-pacing for CRT resulting in extended battery life.
2) Physiologic AV interval modulation by the patient (especially during exercise).
3) More physiologic intrinsic RV contraction.

9. List the main new features of the invention (250 words or less):

Previous methods for achieving fusion pacing relied on sensing intrinsic RV activation. This invention allows for pre-excitation of the LV with respect to the intrinsic RVsense based on the timing of the previous A-RVsense and the desired amount of LV pre-excitation with respect to the RVsense.

10. Has the invention been built or tried? No

11. Has the invention been sold, offered for sale, used for profit, disclosed in a printed publication or otherwise publicly disclosed? No

    If so, what was the approximate date?

12. List any references that you believe may be relevant to the invention:

Medtronic patent application P-8968 by Hill.
[redacted] et. al.
[redacted]
US P[redacted].

13. Please describe in detail the problem(s) your invention solves, how others have addressed this problem and the advantages and/or novelty of your invention over presently known devices/systems/processes/methods. Please list and/or attach electronic copies of known relevant past work (by Medtronic or others) including any patents, publications, and/or other background materials, e.g., similar devices or products.

This invention allows for fusion pacing in cases where the LV must be pre-excited before the RV sense occurs. Hill describes fusion pacing in the context of the LV being paced after the RV sense in P-8968. However it is conceivable and probable that the LV pacing spike will need to occur prior to the RV sense because of LV lead placement on the epicardium. Furthermore, it is conceivable that reliance on an RV sense to trigger an LV pace for the same beat may result in an LV contraction that is delayed, due to processing time required by the sense-amplifier to sense the RV activation and then pace the LV (conceivably there could be a delay up to 30ms from RVsense to LVpace). This method assumes a reasonable amount of AV stability beat to beat. It uses the previous A-RVsense time as the assumed next A-RVsense time, and paces the LV at a time interval determined from the A event such that the desired amount of LV-pre-excitation is achieved with respect to the RV sense.

Th[redacted]n address fusion pacing in the context of bi-ventricular sensing. In these patents/applications, they take great pains to avoid fusion by withholding pacing in the opposite chamber if sensing occurs in the current chamber.

14. Please provide a complete description of your invention and its operation including all possible uses of your invention. Please include or incorporate electronic copies of any reports, documents, notebook pages, sketches, prints, photographs and/or illustrations that help support your invention.

For this disclosure, an A event (termed "A") is an A sense or an A pace. It could be in the RA or the LA. Furthermore, an RV sense is RVs, an RV pace is RVp, an LV sense is LVs, and an LV pace is LVp. The amount of LV pre-excitation desired with respect to the RVs is programmed as the LV pre-excitation time (LV_{pet}). On a beat by beat basis, the ARVs interval is recorded. For each beat n, the ALVp is computed as $ALVp_n = ARVs_{n-1} - LV_{pet}$.

Furthermore, this algorithm could be expanded to look at multiple ARVs times to predict the next ALVp. Methods for doing this include averages or weighted averages (e.g. time weighted, with the most recent intervals carrying more weight) or more advanced signal prediction algorithms which might account for mean ARVs intervals as well as variability and slope of beat to beat trends in AVRs to predict ALVp

The timing of the LVp with respect to the RVs could be monitored on a beat by beat basis to be sure that the actual LV_{pet} is close to the desired or programmed LV_{pet}. If necessary, the ALVp could be adjusted to consistently achieve the desired LV_{pet}. This could be averaged over a number of beats.

Different ARVs intervals could be used depending on if the A event is paced or sensed.

This method could be adapted to RV fusion as well, defining an RV_{pet} with respect to an LV sense. This may apply to RBBB patients.

Inventor(s) Signature(s)

John Ruy

Tom Mullen

Signature

Date